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| 10/087,014 | 03/01/2002 | Henrik Hansen | 12013/59301 | 2646 |
| 23838 | 7590 | 11/24/2003 | EXAMINER | |
| KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005 | | | MICRENER, JENNIFER KOLB | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1762 | |

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,014

Applicant(s)

HANSEN ET AL.

Examiner

Jennifer Kolb Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 311/02 & 311/03
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19 and 25-28, drawn to a method of coating, classified in class 427, subclass 242.
 - II. Claims 20-24, drawn to computer readable medium, classified in class 717.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, functions, and effects. A coating method is unrelated to a computer readable storage medium.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Fred Grasso a provisional election was made without traverse to prosecute the invention of Group I, claims 1-19 and 25-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 requires rotation of the drum to tumble the medical implants, which requires the implants to "bounce" within the drum to enable even coating. Claims 14 and 15,

however, require maintenance of the implants aloft within the drum. It is not clear to Examiner how the rotation of the drum can act to tumble the implants if the implants are maintained in an aloft position within the drum, i.e., not contacting the inner surfaces of the drum. A drum rotating around a medical implant that is suspended aloft within it will not affect the outcome of the coating operation.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-4 and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwarz et al. (US 6,368,658 B1).

Regarding claims 1 and 25, Schwarz et al. teaches a method for coating implantable medical devices (col. 2, line 1) comprising tumbling the devices in a coating chamber (see Figures) and spraying a coating substance to said chamber to coat said implantable devices (col. 2, line 4). The coating substance of Schwarz may include a therapeutic agent (col. 4, line 15).

Examiner notes that Applicant requires coating to occur in a rotatable drum in claim 1, however there is no active method step of rotating said drum. The coating chamber of

Schwarz is a drum, and it is Examiner's position that said drum is inherently *capable* of being rotated.

Schwarz teaches that there is a rotating, planar, metal or ceramic plate in the lower portion of the coating drum chamber, from which the medical devices are repeatedly bounced during the coating operation (col. 7, line 64; col. 8, lines 5, 9, 26, 58, and 65).

This plate acts as a coating pan as required by Applicant in claim 25.

Schwarz teaches the use of jets of air (abstract; throughout), which suspend the medical implants, as required by claim 25.

Regarding claims 2-4 and 26-28, Schwarz teaches the use of jets of air (abstract; throughout), which suspend the medical implant and which will inherently aid in drying volatile coating solvents. Air, defined by Schwarz, may be any suitable gas stream, such as argon, an inert gas (col. 3, line 21). The jets of air do not continue indefinitely and are thus "periodic".

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. (6,607,598) in view of Forster (4,581,242).

Schwarz '598 teaches a substantially similar method as disclosed by Schwarz '658, above, i.e., a method of coating implantable medical devices in a coating chamber using spray coating techniques.

In addition, Schwarz '598 teaches that medical devices may be coated by pan-coating operations (col. 17, lines 35-40), but Schwarz fails to specifically teach the elements of

a pan coating operation. It would have been obvious to one of ordinary skill in the art to look to the art of pan-coating for such elements to perform the operation disclosed by Schwarz '598.

Forster is cited for teaching the coating of pharmaceutical substrates and other small articles (col. 1, line 68) using a pan coating method (col. 2; throughout).

The pan of Forster, with articles to be coated therein, is rotated about a rotating axis (col. 2, line 27). A coating substance is sprayed into the rotating pan onto the tumbling articles (col. 2, line 57).

Since Schwarz '598 teaches coating medical implants, such as stents, which are small articles, in pan-coating operations and Forster teaches that pan coaters are useful in coating small articles by rotating about an axis and spraying the coating composition therein, Forster would have reasonably suggested the specifics of his pan-coating method in the pan-coating method of Schwarz. It would have been obvious to one of ordinary skill in the art to use the teachings of Forster in the method of Schwarz to provide Schwarz '598 with a suitable procedure for pan coating small articles such as stents because Forster's method is suitable for small articles useful in the medical field where precise dosing and sterile conditions are required.

Regarding claim 6, the pan coater drum of Forster is rotated about its longitudinal axis.

Regarding claims 7 and 12, Schwarz '598 and Forster both teach the use of air, a compressible fluid, blown into the coating pan, which dries the coating (col. 13, line 44).

Regarding claim 8, Schwarz '598 teaches multiple layers (col. 7, line 40).

Regarding claims 9-10, Example 1 of Schwarz outlines a process in which the medical devices are subjected to air, a compressible fluid, at a temperature of 20-90 °C before the coating step, encompassing the range claimed by Applicant. Regarding claim 11, body temperature lies within the temperature range of Schwarz. It is Examiner's position that body temperature is a "working temperature" of the therapeutic drugs to be effective upon human implantation. Regarding claim 13, Schwarz teaches a coating operation temperature of 0-200 °C (col. 10, line 8), which would meet the limitation of heating the drum before, during, and after spraying of the therapeutic agent to maintain such a temperature.

Regarding claim 14, Forster teaches blowing air up through the articles in the coating pan and Schwarz teaches the use of such forced air, blown through the medical articles in his coating pan, to suspend the medical implants to provide defect-free coatings as they are held aloft. Since Schwarz teaches pan coating and air-suspension coating and Forster teaches the use of forced air during rotating pan coating, Schwarz would have reasonably suggested the use of Forster's forced air to suspend the articles in the same manner.

Regarding claims 15-16, Schwarz teaches the use of inert gas as the "air" and periodic injection of air, as outlined above.

Regarding claims 17-18, both Schwarz (col. 8) and Forster (col. 2, line 26) require perforations in the drum for entry of the coating substance and compressible fluid.

Regarding claim 19, while the references fail to specifically teach recycling the therapeutic agent, Examiner notes that pharmaceuticals are very expensive. In a spray coating operation, a large quantity of coating material is "lost" and misses its targets. It is Examiner's position that one of ordinary skill in the art would provide a recycling operation to recover the lost pharmaceuticals to be used in a later coating operation so as to maximize manufacturing profits.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Laube teaches pan-coating medical implants. Williamitis teaches tumbling catheters with coating solution.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number, through December 9, 2003, is 703-306-5462. After December 10, 2003, her new

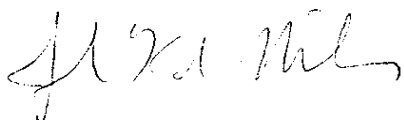
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telephone number will be 571-272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
November 14, 2003